1. Drug Safety Concerns in India – S & T

The recent deaths of children due to consumption of contaminated cough syrup have exposed critical gaps in India's pharmaceutical safety oversight. At least 20 children, mostly under five years of age, died after consuming contaminated Coldrif cough syrup. Tests revealed the syrup contained 48% diethylene glycol (DEG) (an industrial solvent) 480 times higher than the permissible limit of 0.1%. DEG, commonly used in antifreeze and brake fluid, is lethal if ingested, leading to acute kidney and liver failure. The tragedy underscores glaring lapses in drug quality checks and supply chain oversight, calling for urgent reforms. Highly toxic - It causes renal failure, metabolic acidosis, and neurological damage.

Issues with the Drug Safety

Regulatory Challenges - India's dual control system, Central Drugs Standard Control Organisation (CDSCO) setting national policy at the Centre and State Drug Controllers handling enforcement leads to fragmented enforcement. Inconsistent inspection protocols across states allow some manufacturers to escape scrutiny. Weak inter-agency coordination prevents timely sharing of alerts on contaminated batches.

Drugs and Cosmetics Act, 1940

Purpose - Regulates import, manufacture, distribution, and sale of drugs and cosmetics in India to ensure safety, efficacy, and quality. Protects public health by preventing adulterated or spurious medicines from reaching consumers.

Key Features -

Licensing - Mandatory for all drug manufacturers, wholesalers, and retailers.

Standards & Quality - Prescribes Good Manufacturing Practices (GMP), standards for raw materials, and testing procedures.

Prohibitions - Bans adulterated, spurious, misbranded, or unsafe drugs.

Penalties - Provides criminal prosecution, fines, and license cancellation for violations.

Schedule M - Part of the Act outlining GMP for pharmaceutical manufacturing, including equipment, hygiene, documentation, and quality control.

Recent Updates - Revised Schedule M (2023–24) aligns with WHO-GMP standards, introduces Quality Risk Management, ALCOA+ data integrity, and pharmacovigilance systems.

Aims to strengthen drug safety oversight and prevent incidents like contaminated cough syrups.

Weak compliance with Good Manufacturing Practices (GMP) - Many units still operate without registering under the revised GMP norms (Schedule M) under the Drugs and Cosmetics Act, 1940 despite multiple extensions by the government.

Infrastructure Gaps - A 2023 parliamentary review revealed that nearly half of India's state drug testing laboratories lack proper equipment or qualified analysts for effective surveillance. Compliance with revised Schedule M norms requires investment in infrastructure, modern labs, and trained personnel. Outdated or under-equipped labs struggle to detect toxins like DEG and EG reliably, increasing risk of contamination going unnoticed. Lack of financial support mechanisms (subsidies, low-interest loans) slows adoption of quality standards.

Manufacturing Issues -

1. Poor testing of raw materials allows contaminated inputs to enter production.
2. Supply chain lapses lead to substandard or mislabelled ingredients being used.
3. Inadequate cleaning of equipment can cause cross-batch contamination.
4. Some manufacturers intentionally replace pharmaceutical-grade solvents with cheaper industrial alternatives to cut costs.

Dissatisfactory Pharmacovigilance - Incidents highlight broader gaps in pharmacovigilance, adverse drug reporting, and quality assurance mechanisms. Weak post-marketing surveillance increases the risk of other medicines and supplements causing harm, emphasizing the need for a robust national drug safety system.

Key Government Initiatives and Measures - and Other Institutions Response

Strict Enforcement of Revised Schedule M Norms - The Union Health Ministry has mandated compliance with revised Schedule M under the Drugs and Cosmetics Act, 1940, which sets Good Manufacturing Practices (GMP) and quality standards for drug production.
Revisions (2023–24) align Indian GMP with WHO and PIC/S standards, including -

1. **Pharmaceutical Quality System (PQS) -** Mandatory adoption of a structured quality and risk management framework across all manufacturing stages.
2. **Quality Risk Management (QRM) for all production stages -** Identification and mitigation of product risks through scientific and evidence-based evaluation.
3. **Data integrity under ALCOA+ principles -** All records must be Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, and Available.
4. **Process Validation -** Lifecycle-based validation (Design, Installation, Operation, Performance Qualification).

SHRESTH (State Health Regulatory Excellence Index) - A newer initiative launched by the Union Health Ministry / CDSCO to benchmark and drive improvements in state drug regulatory authorities
Objective - To enhance consistency, accountability, and quality across states. Under SHRESTH, states are assessed on performance, capacity, regulatory standards etc., which helps in directing support and reform.
Pharmacovigilance Programme of India (PvPI) - Launched in July 2010 under Ministry of Health & Family Welfare, with the goal of monitoring and improving drug safety by collecting and analyzing adverse drug reaction (ADR) reports. PvPI collects, collates, and analyzes ADR reports from a network of ADR monitoring centres across India. It sends recommendations/advisories/alerts to CDSCO for regulatory action.

Broader Implications

Legal and Constitutional Dimension - Article 21 guarantees the right to life and personal safety, which extends to access to safe medicines. Failure to prevent deaths due to toxic drugs represents a violation of constitutional rights, exposing the state to legal scrutiny.
Impact on Global Reputation and Trade - India, dubbed the "Pharmacy of the World", can faces potential credibility loss in international markets. Previous incidents, such as child deaths in Gambia and Uzbekistan linked to Indian syrups, have already prompted WHO alerts. Long-term trust erosion could affect India's position as a major supplier of generic medicines, particularly to African and Latin American countries.
Economic and Sectoral Repercussions - The credibility loss can impose financial losses on pharmaceutical firms and reduce contributions to GDP (Pharma sector contributes over 2% to India's GDP). Increased regulatory scrutiny may require significant investment in testing infrastructure, impacting profitability of smaller firms.
Humanitarian Crisis and Public Confidence Erosion - Repeated incidents of contaminated medicines erode trust in the healthcare system, making parents hesitant to seek timely medical care for their children. Such incidents can reduce vaccine uptake and confidence in routine pediatric care, amplifying health risks.

Way Forward

1. **Unified Regulatory Authority** - Establish a single, autonomous national drug authority to centralize enforcement, harmonize standards across states, and maintain a real-time database of inspections and batch testing.
2. **Strict Enforcement of Revised GMP (Schedule M) -** Ensure all manufacturing units comply with revised Schedule M norms, including Quality Risk Management, ALCOA+ data integrity, and robust pharmacovigilance.

3. **Risk-Based and Surprise Inspections -** Conduct unannounced audits of pharmaceutical units to deter malpractice and ensure adherence to quality standards.
4. **Fast-Track Prosecution and Stricter Penalties -** Expedite legal action against negligent manufacturers and prescribing doctors, with criminal prosecution, fines, and license cancellations
5. **Real-Time Pharmacovigilance -** Implement a nationwide adverse event reporting system linking hospitals, pharmacies, and regulators for early detection of unsafe drugs.
6. **Adopt Global Best Practices -** Align regulatory mechanisms with WHO guidelines, PIC/S standards, and international testing protocols, ensuring all batches—domestic or export—are independently verified before release.
7. **Modernize Testing Infrastructure -** Upgrade state laboratories with advanced analytical instruments and trained personnel to detect contaminants like DEG and EG efficiently.
8. **Public Awareness and Prescribing Guidelines -** Educate parents and medical practitioners on safe pediatric medication practices and discourage irrational use of cough syrups in children under five.

Conclusion

Robust enforcement, centralized oversight, and adoption of global best practices are essential to prevent future tragedies; India's credibility as the "pharmacy of the world" depends on safeguarding citizens from preventable drug-related risks.

Source - https - //www.business-standard.com/india-news/cough-syrup-deaths-sc-agrees-to-hear-pil-seeking-cbi-probe-safety-review-125100900408_1.html